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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,733	07/20/2001	Leo Martis	DI-4389 DIV	2820

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EXAMINER	
LUKTON, DAVID	

ART UNIT	PAPER NUMBER
1653	5

DATE MAILED: 03/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/909,733	Martis
Examiner	**Art Unit**
David Lukton	1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Feb 1, 2002 .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 2-8 and 19-31 is/are pending in the application.

4a) Of the above, claim(s) 19-31 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 2-8 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

Pursuant to the directives of paper No. 4 (filed 2/1/02), claims 1 and 9-18 have been cancelled, and claims 19-31 added. Claims 2-8 and 19-31 are pending. Claims 19-31 are withdrawn from consideration, however. Claim 2 mandates that the glucose concentration be limited to 1-8%, and that the pH be limited to 4.0 - 5.5. The ramifications of these differences are substantial. First, claim 19 does not actually require that one have two different solutions. The "first part" does not preclude the presence of peptides, and the "second part" does not preclude the presence of glucose. While the same can be said of claim 2, claim 2 mandates that there be a difference in pH. So claim 2 does in effect mandate that the two solutions cannot be the same. Claim 19, on the other hand, encompasses the possibility of having two sterile bags which contain the identical solution. Second, the search for the invention of claim 19 would have to encompass solutions in which the pH of the glucose is closer to physiological. Hemodialysis solutions would also be potentially encompassed. Third, and perhaps most important, there is no upper limit on the concentration of glucose in claim 19. Thus, a search for the invention of claim 19 would have to proceed outside the realm of peritoneal dialysis. For example, glucose might be adminstered to a hypoglycemic patient. Or it could be used as part of a total parenteral nutrition program. Or the glucose could be stored as a stock solution at high concentration. This solution could then be used for medical applications, or research applications.

While claim 19 will not be rejoined, the possibility of rejoining claim 23 or 26 may be considered at a later time. In addition, it is likely that a claim would be rejoined if it mandated the presence of a solution that was found allowable in parent application 07/995,106.

*

Claims 2-8 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 2 recites the following:

  "a first part housed in a first structure including approximately 1 to about 8% dextrose..."

  First, it is not clear what "including" refers to. Does this refer to the "first part" or to the "first structure"...? Moreover, there is no recitation of, or requirement for a solution at this point. While not necessarily resolving all issues, the following would be better than what is currently recited:

  A two part peritoneal dialysis solution... comprising...
  a first part housed in a first structure, wherein said first part includes a solution which contains 1.0 - 8% (w/v) dextrose...

- Claim 2 recites "approximately 1.0 to about 8% dextrose...". This renders the claim indefinite as to the actual lower and upper limit. Is the lower limit 1% or is it, e.g., 0.7%....? Is the upper limit 8% or is it e.g., 10%...? This also concerns claims 4, 5, 6, and 8.

- In claim 8, it is recited that the peptides are "approximately 2" amino acids in length. What is meant by this. Does this, or does this not encompass "polypeptides" that

are "one" amino acid long?

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The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claim 2 is rejected under 35 U.S.C. §103 as being unpatentable over Okamoto (USP 4,880,629) in view of Klein USP (5,039,609).

Okamoto discloses (e.g., col 12, lines 66-67) a peritoneal dialysis solution in which the glucose is present to the extent of 0.005 - 78 g/liter, and the pH is 5.5-6.5. The reference does not suggest that the solution be present in a container which is in proximity to a second container which contains a peptide solution.

Klein teaches (e.g., col 4, line 21+) compositions comprising peptides for peritoneal dialysis. In addition, the reference teaches (col 12, line 40+) that the peptides can be

"combined with any osmotically balanced aqueous solution [that is] appropriate...". Klein also does not teach that the peptide solutions should be present in a container which is in proximity to a second container which contains glucose.

There are three separate grounds of rejection here. First, it is asserted that it would have been obvious to combine the two solutions (of Okamoto and of Klein) for additive effects. Klein provides some motivation for doing this, as indicated. However, whether or not applicants agree with this first assertion by the examiner, there is a second assertion, which is that it would have been obvious to use the two solutions sequentially for additive effects. Even if it is true that applicants have obtained some sort of "unexpected results" for the combination of the two solutions (glucose and peptides), it does not necessarily follow therefrom that the property of "unexpectedness" extends to the sequential use of the two solutions for dialysis. There is a third perspective on this, which is that claim 2 does not actually require that the two solutions be used on the same patient, or that their use be recommended by the same physician. Claim 2 only requires that at one location there exists a "first structure", and that at another location there exists a "second structure". The "first structure" and the "second structure" could both be present in the same supply room on, e.g., the third floor of a hospital. Or the "first structure" might be present on the second floor of a hospital, and the "second structure" might be present on the 10th floor of the same hospital. Or the "first structure" might be present in a hospital located in Philadelphia,

and the "second structure" might be present in a hospital located in Chicago. The assertion is that some physicians prefer to use glucose, and others prefer peptides. If two containers are present within, e.g., 3000 miles of one another, they would still meet the requirements of claim 2.

Thus, the claim is rendered obvious.

*

Claims 2-3 are are rejected under 35 U.S.C. §103 as being unpatentable over Klein (U.S. Patent 5,039,609) in view of Steudle (U.S. Patent 5,011,826).

As indicated, Klein teaches that peptides can be used in a dialysis solution. The reference also teaches (e.g., col 13, table 2) that sodium, calcium, magnesium, chloride and lactate may be present. Klein does not teach that glucose may be combined in the same solution.

Steudle teaches (col 4, lines 51-59) that glucose can be combined with peptides in a peritoneal dialysis solution. Although Klein does not suggest combination of glucose with peptides, this combination is taught by Steudle. Thus, the claims are rendered obvious.

*

USP 4,168,337 was stricken from the IDS. The author of this is not Gordon, and it appears that the patent number is in error. Similarly, USP 3,939,261 is in error. EP 0,431,465 and EP 0,170,275 were stricken because of the absence of a translation. The remaining references that were stricken were so treated because they were not received.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton [phone number (703)308-3213].

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1600